DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 19, 2015

Derma Sciences Incorporated
Ms. Sharmini Atheray
Vice President Quality and Regulatory Affairs
104 Shorting Road
Toronto, Ontario M1S 3S4
Canada

Re: K150985
Trade/Device Name: Medihoney Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 15, 2015
Received: October 19, 2015

Dear Ms. Atheray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150985

Device Name
Medihoney Wound Gel

Indications for Use *(Describe)*
Derma Sciences Medihoney Wound Gel helps maintain moist environment. Moist wound environment was shown to be conducive to wound healing.

For over the counter use, Medihoney Wound Gel with Active Leptospermum Honey may be used for:

-minor abrasions
-lacerations
-minor cuts
-minor scalds and burns

Under the supervision of a healthcare professional, Medihoney Wound Gel helps maintain a moist environment. Moist wound environment was shown to be conducive to wound healing and are indicated for non-draining to moderately exuding wounds. The Medihoney Gel Wound Dressings are intended for the management of the following:

-diabetic foot ulcers
-leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
-pressure ulcers / sores (partial and full thickness)
-1st and 2nd degree partial thickness burns
-donor sites, traumatic and surgical wounds

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for the
Derma Sciences, Inc.
Medihoney Wound Gel

Date Prepared: September 15, 2015

1. SUBMITTER/510(K) HOLDER/CONTACT PERSON

Sharmini Atheray
Derma Sciences, Inc.
104 Shorting Road,
Toronto, Ontario M1S 3S4
416-299-4003 x245

satheray@dermasciences.com

2. DEVICE NAME

Proprietary Name:	Medihoney Wound Gel
Common/Usual Name:	Wound Dressing
Classification Name:	Wound Dressing

3. PREDICATE DEVICES

The Derma Sciences Medihoney Wound Gel is substantially equivalent in design, function and intended use to the original Medihoney Gel Dressings With Active Manuka (K101793) and the BioTD S.A. Ross Ru Skin Discontinuities (K131176).

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4. DEVICE DESCRIPTION

The primary component of the Medihoney Wound Gel is Active Leptospermum Honey. The purpose of this 510(k) is to obtain clearance for a slightly modified version of the Derma Sciences Medihoney Wound Gel Dressings subject of K101793. The original Medihoney Gel Dressings contain Active Manuka Honey, Myristyl Myristate, and Plantacare. The proposed Medihoney Gel Dressings contains a slightly different formulation than the original Medihoney Gel Dressings in that Sodium Benzoate has been added as a preservative to the formulation. Due to the limitations in hermetically sealing the Wound Gel jar lids, this product will be Gamma Irradiated at 25-45kGy dosage, which will help reduce the product bioburden. However this product will not be claimed sterile. Gamma Irradiation will aid in reducing the product bioburden and the preservative Sodium Benzoate will act as a preservative within the gel.

5. INTENDED USE

The Derma Sciences Medihoney Wound Gel helps maintain a moist environment. Moist wound environment was shown to be conducive to wound healing.

For over the counter use, Medihoney Wound Gel may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

Under the supervision of a healthcare professional, Medihoney Wound Gel helps maintain a moist environment. Moist wound environment was shown to be conducive to wound healing and are indicated for non-draining to moderately exuding wounds. The Medihoney Wound Gel is intended for the management of the following:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The indications for use are identical to the original 510(k) for the Medihoney Wound Gel. The Medihoney Wound Gel formulation has been slightly modified to add sodium benzoate as a preservative. This slight modification does not affect safety or effectiveness since sodium benzoate is used to preserve the formulation and does not affect the intended use of the Medihoney Wound Gel. The proposed Medihoney Wound Gel is subjected to gamma irradiation, however due to limitations in hermetically sealing the Wound Gel jar lid, the product is not considered sterile. Sodium Benzoate preservative present within the gel will act as a preservative within the gel.

The technological characteristics of the Medihoney Wound Gel are essentially identical to the predicate since the entire formulation is identical except for the addition of a preservative, sodium benzoate which does not affect the function of the gel. In addition, sodium benzoate has been designated by FDA as GRAS under Sec. 184.1733 Sodium benzoate. As stated above, the only change that is the subject of this 510(k) submission, is the non-sterile status and the addition of sodium benzoate which does not affect function, indications, safety or effectiveness.

The Medihoney Wound Gel is substantially equivalent in indications and technological characteristics to the original Medihoney Wound Gel subject of K101793 and the BioTD S.A. Ross Ru Skin Discontinuities (K131176) since they all consist of a gel component that provides a moist wound component in the formulation.

The proposed Medihoney Wound Gel Dressings and the predicate devices are identical in that they are all composed of a gel dressing that contains a component in the formulation that contributes to a moist wound environment and used in a variety of wound types. The proposed and predicate devices are identical in functional and technological characteristics since they are the same device with the exception of a slight modification to the formulation. The slight difference in materials of manufacture for the Medihoney Wound Gel and the predicate devices does not affect safety or effectiveness since sodium benzoate has been added to the formulation simply as a preservative. As stated above, Sodium Benzoate has been added to preserve the formulation. The proposed Medihoney Wound Gel is offered non-sterile since during the gamma irradiation the Wound Gel jar lid is not hermetically sealed, therefore the Wound Gel is considered non-sterile. However, the gamma irradiation process and the Sodium Benzoate serve to reduce the bioburden of the product and preserve the product from further contamination. In addition, there are many wound gel products on the market that are provided non-sterile including the predicate BioTD, S.A.Ross Ru Skin Discontinuities (K131176).

The operational characteristics of the proposed Medihoney Wound Gel Dressings are identical to the predicate devices in that they are intended to be used as primary or secondary coverings for the management of a variety of wounds. They provide a moist wound environment conducive to wound healing. The technological characteristics of the proposed Medihoney Wound Gel and the predicate device are identical in that they are dressings that include a moist gel like component and are suitable for the management of a variety of wounds.

The instructions for Medihoney Wound Gel is identical to that cleared for the Medihoney Wound Gel predicate device. However, the predicate Medihoney Wound Gel was provided in single use application, whereas the proposed Medihoney Wound Gel will be provided in a multiple use jar for single patient use. Derma Sciences believes that the above rationale and the comparison table demonstrate substantial equivalence of the proposed Medihoney Wound Gel to the original Medihoney Wound Gel (K101793).

In conclusion, the Derma Sciences Medihoney Wound Gel is substantially equivalent to the predicate devices with respect to material composition, device characteristics and intended use since the addition of a preservative does not affect safety or effectiveness of the Wound Gel as it acts only as a preservative in the formulation. Therefore, the technological characteristics support the substantial equivalence to the original Medihoney dressings and to the predicate devices listed above that have similar indications for use.

7. PERFORMANCE TESTING

The Medihoney Wound Gel has been subjected to cytotoxicity, sensitization, irritation and implantation testing. This testing supports the safe use of Medihoney Wound Gel for its proposed indications for use. In addition, the original Medihoney Wound Gel devices have been on the market since 2011 with no unanticipated adverse events.

The extensive safety and effectiveness evidence demonstrated in the safe use of the original Medihoney Wound Gel cleared in 2011 (K101973) supports the safe use for the proposed indications for use. The proposed Medihoney Wound Gel is safe, effective, and is substantially equivalent to the original Medihoney Wound Gel since the formulation is essentially identical with the exception of the addition of a preservative.